Hysterosalpingogram Confirmation for Essure® Permanent Birth Control Device Placement and Occlusion

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Abstract

The Essure® hysteroscopic sterilization system is a minimally invasive technique that involves the placement of micro-inserts into the fallopian tubes. These micro-inserts contain polyethylene terephthalate (PET) fibers, which cause a benign inflammatory response, occlude the fallopian tubes, and cause permanent sterilization. The United States Food and Drug Administration (FDA) requires that the patient undergo follow-up hysterosalpingography three months after device placement to prove device retention, determine the location of the inserts, and ensure tubal occlusion.

Many imaging professionals are not properly educated on the procedures and images required in the manufacturer recommended follow-up hysterosalpingography protocol. In this study, data from these examinations at a large, mid-west university hospital were analyzed, and descriptive statistics about the frequency of images obtained and complications noted in the radiologist's reports are presented. The data was also evaluated for trends relating to the technical quality of the images.

Of 428 images obtained in 130 sample exams, 74 exams included a preliminary scout image, 55 exams included a minimal fill image, 88 exams included a partial fill image, 119 exams included a total fill image, 46 exams included a right magnification image, and 46 exams included a left magnification Seventy percent of the cases included 2,3, or 4 images, and about 12% of cases only included one image for the radiologist to evaluate. However, only 9 reports

contained mentions of limitations in diagnosis due to the number or quality of the images provided for interpretation.

Twenty-two percent of the cases included fundal images of the uterus. Parts of the reproductive anatomy including the vagina, uterus, and cervix were clipped off in 28% of the cases, and in a further 18%, the gynecologist failed to remove the speculum prior to exposure, resulting in incomplete visualization of reproductive anatomy. In 9% of the exams, one of more of the images was considered blurry during this secondary analysis. The most frequent technical error committed during these exams was failure to use a lead marker to denote anatomic side; 52% of cases were not marked with a lead marker.

Chapter One

The Problem

There are many different methods of birth control available for women of reproductive age. Their indications for use vary based many factors including patient age, method permanency, and associated costs. Some of the most common and inexpensive forms of temporary birth control include barrier methods. This category includes both male and female condoms, diaphragms, and cervical caps, and these methods can be up to 85% effective if used properly.[1] Another popular method of contraception is the use of hormones to temporarily cease ovulation. These hormones can be administered by an injection, an implanted device, or a pill that is ingested daily. When taken as directed, these methods can be up to 99% effective.[1] When women no longer wish to have the option to become pregnant, a permanent method of birth control can be considered. There are several types of permanent female sterilization procedures. Both tubal ligation and hysterectomy procedures are surgical in nature and require the use of general anesthesia. However, these forms of birth control are over 99% effective in the prevention of pregnancy.[1]

One of the only permanent birth control systems currently approved by the United States Food and Drug Administration (FDA) is the Essure® hysteroscopic sterilization system.[2] According to Conceptus, the manufacturer of this device, this is a minimally invasive, transvaginal procedure which is usually done in an outpatient setting without the use of general anesthesia.[1] A small, flexible coil, called a micro-insert, is placed into each fallopian tube. These micro-inserts are

comprised of a stainless steel inner coil, a Nitinol expanding outer coil, and polyethylene terephthalate (PET) fibers that are wound into the inner coil. Each micro-insert is extended into the uterus through a disposable delivery system provided by Conceptus (Figure 1).[1]

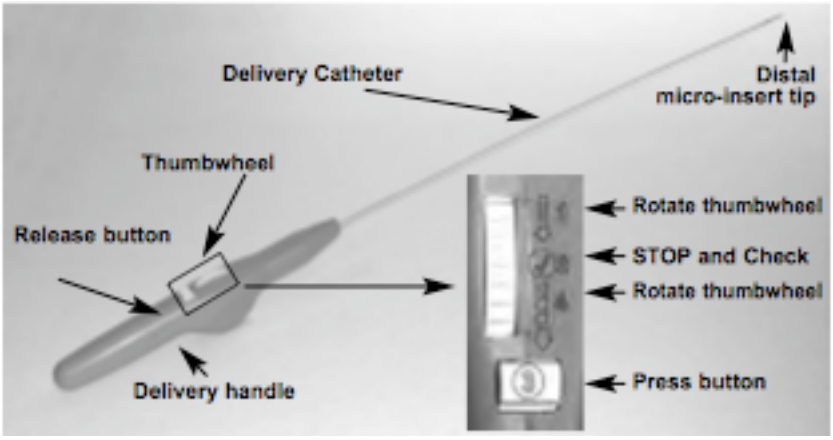

Figure 1 – Essure® Delivery System (Conceptus Inc.)

The Essure® coil is attached to the delivery wire of this disposable delivery system. Prior to device placement, the coil is wound-down and sheathed by a flexible catheter (Figure 2).[1]

Figure 2 – Coil Appearance Before Placement (Conceptus Inc.)

If intravenous sedation is not required, micro-insert placement is performed as an outpatient procedure at the physician's office. Before the Essure® delivery system is introduced, the physician places a speculum into the vagina to allow access to the cervix. A sterile hysteroscope is then placed through the cervix and into the uterine cavity. This hysteroscope employs the use of a small camera and is used to position the device at one of the fallopian tube

ostium.[2] The Essure® delivery system is advanced through the sealing cap on the hysteroscope working channel, and the physician rotates the thumbwheel portion of the delivery system to place the Essure® device in the proximal portion of the fallopian tube (Figure 3).[1]

Figure 3 – Essure® Delivery System Inserted Through Sealing Cap of Hysteroscope (Conceptus Inc.)

Optimal positioning of the coils is marked when the device spans the utero-tubal junction; ideally, three to eight outer coils should trail into the uterus.[1] This placement is desirable because the portion of the device trailing into the uterine cavity aids in device anchoring.[1] After the device is deployed, the outer coil expands to mold to the varied diameters of the fallopian tube and anchors the device in place (Figure 4).[1]

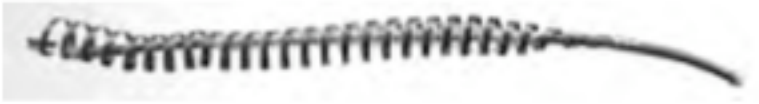

Figure 4 – **Coil Appearance After Placement** (Conceptus Inc.)

The PET fibers of the inner coil induce a benign inflammatory response and eventual fibrosis of the intramural tubal lumen, thereby aiding in device retention and causing tubal occlusion.[1,2,3]

On the day of device placement, complications arising from the Essure® device include band detachment, vasovagal responses, pain, cramping, nausea and vomiting, and dizziness.[1] Other complications that may arise within a year of placement have been recorded, such as cramps, generalized pain, back pain, headache, and dysmenorrhea.[1,4] Some patient's may develop an infection or salpingitis, and in some cases, become pregnant if device placement is not optimal or the patient does not comply with alternative birth control methods until a three month follow-up hysterosalpingogram (HSG) has been performed.[1,2] However, during the phase II and pivotal trials, reliance on the device for occlusion was 97% and zero pregnancies were recorded when proper device placement was obtained.[1,2]

Because of the minimally invasive nature of this procedure, this technique has steadily increased in popularity since its introduction in November of 2002.[5] There are no abdominal incisions or scars, and women are usually able to return to daily activities with a high rate of patient tolerance and satisfaction.[6] In addition, this form of birth control does not require the use of hormones, which increases its appeal as an alternative form of contraception.[6]

As part of the FDA approval guidelines, the Essure® package labeling includes a requirement for a three month follow-up hysterosalpingogram to prove device retention, determine the location of the inserts, and ensure the occlusion of the fallopian tubes.[1,5]

The most common technique for doing HSG examinations is the Kidde technique. With the patient in the lithotomy position, a sterile speculum is

inserted into the vagina to provide clear visualization of the cervix. A tenaculum is placed on the anterior cervical lip, from which the patient may experience slight cramping.[7] An acorn tip is attached to a Kidde cannula, and the tubular end of this tip is inserted into the external cervical os. This tightly seals the external os and prevents contrast leakage into the vagina.(Figure 5).[7]

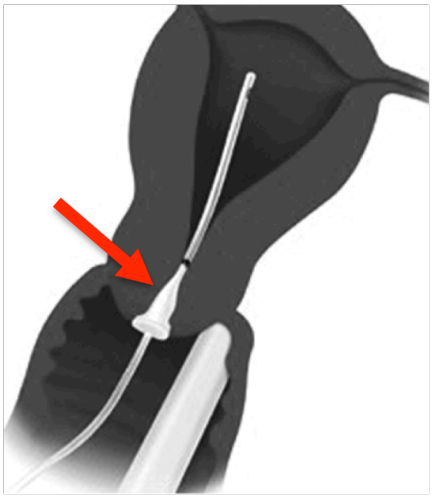

Figure 5 – Kidde Cannula Placement During HSG (Lindheim et al) – HSG procedure; the acorn tip is sitting within the cervix and identified by the red arrow.

As recommended by the manufacturer protocol, prior to contrast introduction, the physician should obtain a scout image with the uterus in a true anteroposterior position to visualize the Essure® device presence and placement.[1] For all images, traction on the tenaculum or rotation of the patient into an oblique position may be necessary to better depict the uterine anatomy in a true anteroposterior position.[7] The iodinated contrast medium is then injected at a slow rate using steady, low pressure to minimize uterine cramping.[1,7] The physician should monitor contrast filling of the uterus with fluoroscopy, and obtain a spot image with minimal contrast fill. This image depicts an adequate cervical

seal and beginning opacification of the uterus.[1] Another spot image is acquired when the uterus is nearly full, but contrast does not yet reach the uterine cornua. The portions of the Essure® coils that trail into the uterine cavity are still visualized.[1] Contrast medium injection is continued until the patient can bear no more pressure.[1,7] This pressure on the uterine cornua is necessary for satisfactory diagnosis of fallopian tube occlusion and to rule out the possibility of contrast passing beyond the Essure devices.[1] Two final magnification views of the right and left Essure® device should be obtained to provide better visualization of device placement and occlusion.[1] With the uterus in a true anteroposterior position, these images should be centered on one of the Essure® devices.[1]

Some facilities utilize other forms of medical imaging to provide a similar means for assessment of occlusion, such as abdominal radiographs, transvaginal ultrasound, and hysterosalpingosonography.[8] However, these techniques are not currently supported by the FDA because they are not able to diagnose fallopian tube patency; hysterosalpingography remains the preferred method of determining tubal occlusion and device placement in the United States.[5]

Many medical personnel are not properly educated on the procedures and images required or the benefits of the images obtained through the recommended follow-up protocol. Because the results of hysterosalpingogram confirmation are critical in the determination of appropriate tubal occlusion, radiologists must be able to assess images of high quality and comparative value

so that their reports can be as consistent and accurate as possible. Therefore, Medical facilities should adopt the recommended post-Essure® hysterosalpingogram protocol provided by the manufacturer to guarantee standardized results and analysis.[5]

Chapter One

Review of Literature

Conceptus, the manufacturer of the Essure® female sterilization system, conducted two separate clinical trials to assess the safety and effectiveness of the Essure® system.[1] Of 745 women included in both the phase II and pivotal trials, placement of at least one Essure® coil was achieved in 682 women. Bilateral placement was successful in 94.6% of cases.[1] Nineteen of 476 patients within the phase II trial experienced wither perforation or expulsion of one or more Essure® devices. This represents 3.99% of the population of the study.[1] Within one year of device placement, 127 of 476 patients experienced some sort of pain associated with device placement, including severe menstrual cramping.[1]

Based on the research conducted in the phase II and pivotal trials, Conceptus recommends a set protocol for the confirmation hysterosalpingogram that is required by the FDA. This HSG confirms tubal occlusion and allows the patient to rely on the devices for contraception. This protocol calls for a "low-flow, low pressure [hysterosalpingogram] performed three months post Essure® placement"[1] to demonstrate correct placement of the micro-inserts and to assess the occlusion of the fallopian tubes. A minimum of six still radiographs should be obtained during the procedure, beginning with a scout image with the uterus in a true anteroposterior position to visualize the Essure® device presence and placement.[1] After this image is assessed, a series of three radiographs demonstrating the increasing fill of the uterine cavity are captured. The fifth and

sixth required radiographs are magnified views of the uterine cornua to determine exact location of the micro-inserts.[1]

Protocol Image	Image Name	Structures Visualized/ Image Importance
Image 1	Scout	Device presence and placement
Image 2	Anteroposterior Minimal Fill	adequate cervical seal and beginning opacification of the uterus
Image 3	Anteroposterior Partial Fill	Contrast does not yet reach the uterine cornua; The portions of the Essure® coils that trail into the uterine cavity are still visualized
Image 4	Anteroposterior Total Fill	Maximum pressure on the uterine cornua; Necessary for satisfactory diagnosis of fallopian tube occlusion and to rule out the possibility of contrast passing beyond the Essure devices
Image 5	Anteroposterior Magnified Right Essure® Device	Larger and more detailed visualization of the devices; determination of the relationship of the coil markers to the uterotubal junction
Image 6	Anteroposterior Magnified Left Essure® Device	Larger and more detailed visualization of the devices; determination of the relationship of the coil markers to the uterotubal junction

Figure 6 – Conceptus-Recommended Protocol Images

Each of these radiographs should clearly show the entire uterine cavity silhouette with the uterine cornua maximally distended.[1] In addition, the fluoroscopy procedures should be completed with the beam entering the patient

as close to anteroposterior as possible. Failure to meet these minimum requirements could result in repetition of the necessary images, which would increase radiation dose, or misdiagnosis of tubal occlusion. This misdiagnosis could lead the patient to rely on the Essure® devices for contraception when one or more fallopian tubes is patent, possibly resulting in unintended pregnancy.[1]

The company suggested protocol also describes the ideal location of the micro-inserts; this positioning is evident when the inner coil crosses the utero-tubal junction. The distal end of the inner coil should sit within the fallopian tube with less than fifty percent of the coil extending proximally into the uterine cavity. (Figure 6).[1]

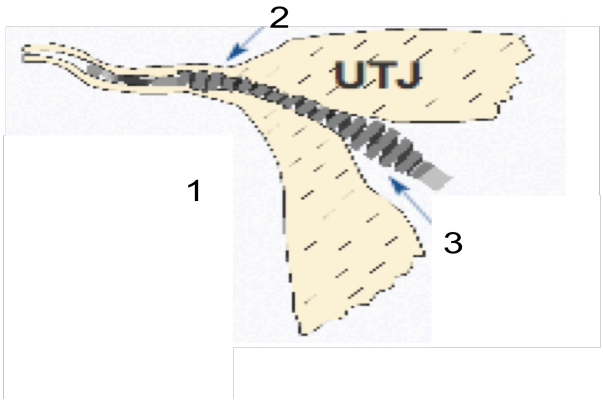

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Figure 7 – Device Placement
1) Device spans the utero-tubal junction. 2) Distal end of the inner coil sits within the fallopian tube. 3) <50% of the coil extends into the uterine cavity.

Conceptus suggests that if this optimal positioning is not successful, the patient should not rely on the Essure® device for contraception. Improper placement could result in unintentional pregnancy even if occlusion is apparent during the follow-up HSG due to potential device expulsion.[1] When assessing occlusion, the radiologist evaluates the presence of contrast in the fallopian tubes

distal to the micro-insert location. The tube is occluded satisfactorily when contrast solution is not visible past the cornua. Patients are advised not to rely on the micro-inserts for contraception if contrast is seen past the distal end of the coils or in the peritoneal cavity.[1]

In a six-year review of the Essure® hysteroscopic sterilization technique, the effectiveness, safety, and complications reported with the use of the device were analyzed.[2] The hysteroscopic procedure involves the transcervical implantation of coiled, double-layered micro-insert devices in the fallopian tubes. This examination is generally performed without the use of anesthesia in an outpatient setting.[2] Post-placement, the white polyethylene terephthalate fibers surrounding the coils trigger the benign growth of tissue into the fallopian tube, causing occlusion and preventing future pregnancies.[2] Three months after the Essure® procedure, a hysterosalpingogram is obtained to determine bilateral coil placement and complete tubal occlusion.[2] This three month waiting period was highly subjective when the system was first implemented, as there was little factual evidence to support the hypothesized rate of tissue growth necessary to occlude the tubes. However, studies have confirmed that up to 99% of patients show evidence of successful tubal occlusion on the three month hysterosalpingogram, even though some patients may be fully occluded within one to two months.[2] Long-term adverse effects are limited; one year post-device placement, 99% of women rated their comfort level at good to excellent.[2] From 1998 to 2007, Conceptus received 169 reports of unintended pregnancies, which equates to 0.1% relative to device sales during that time. In addition, 44% of

these unintended pregnancies can be attributed to patient and physician noncompliance with the follow-up HSG.[2]

A study completed in 2005 was designed to determine the efficacy of hysterosalpingography examinations in determining tubal occlusion.[9] Thirty-two subjects were identified as having Essure® devices placed between April 2003 and February 2004. Of these patients, only nineteen had undergone a three month follow-up hysterosalpingogram due to patient noncompliance.[9] In addition, it is stated that no set protocol was used when obtaining images during the course of this study.[9] Of the women who received the three month follow-up examination, the number of exposures per patient varied greatly, ranging from one spot film to five spot films with an average of 2.4 per examination. The number and types of radiographs that were obtained were chosen according to the preference of the radiologist analyzing the images.[9] Almost half of the patients included in the study received only one anteroposterior image. For these patients, those physicians who reviewed the images agreed that additional oblique images would have improved their evaluation of device placement and degree of tubal occlusion.[9]

A different study utilized a retrospective chart review of eighty-three patients that underwent Essure® device placement in a particular facility from January 2003 to June 2007.[5] It addressed the potential complications that may arise after Essure® device placement. Device movement, nonocclusion, tubal perforation, and structural malfunctions of the coils can be detected on the three month hysterosalpingogram.[5] However, of the 79 patients included in the sample,

only 12.7% received a follow-up HSG, which the researchers note to be alarmingly low. One of 36 patients who received this HSG had unsatisfactory device placement according to the manufacturer recommendations. However, occlusion was confirmed for this patient.[5] This device placement could predispose the patient to device expulsion. Therefore, this patient was counseled to not rely on the device for contraception.[5] There was one documented pregnancy in a patient who was noncompliant and did not receive a follow-up HSG.[5]

Alternative methods to determine device placement are discussed within this study, including pelvic radiology and ultrasonography. However, these imaging modalities are only able to determine device placement and do not prove tubal occlusion.[5] Therefore, the Food and Drug Administration has not approved these imaging modalities for Essure® confirmation; hysterosalpingography remains the required three month confirmation assessment.[5]

Lipman and Famuyide discussed hysterosalpingography and its role in Essure® placement and tubal occlusion confirmation. The hysterosalpingogram required in the Essure® protocol differs significantly from a hysterosalpingogram to evaluate infertility; the confirmation test requires much less pressure and produces minimal discomfort compared to a traditional HSG.[10] Therefore, radiologists must be aware of the appearance of the Essure® coils before and after insertion. The importance of following the recommended protocol set by the Essure® manufacturer and providing detailed radiology reports are also noted.[10] The benefits of confirmation hysterosalpingography should be emphasized with

the patient, noting that the procedure is not finished until this follow-up examination is completed. This procedure is critical because complications caused by placement failure can be diagnosed through evaluation of a hysterosalpingogram.[10]

The Objective

Purpose of this study:

Compare hysterosalpingogram examinations for confirmation of Essure® placement and fallopian tube occlusion in terms of:

1. the number of images obtained versus the recommended protocol
2. mentions of limitations in diagnosis within radiologists' reports
3. instances of technical problems in the images provided for evaluation

Benefits of my research:

Although other facilities and companies have conducted trials to assess the effectiveness of the Essure® device and its resulting complications, most of these studies have very limited sample sizes. My sample of 130 patients will be the largest of any study that I have come across through my research. The results of hysterosalpingogram confirmation are critical in the determination of tubal occlusion, and radiologists must be able to assess images of high quality and comparative value to guarantee standardized results and analysis. Because many imaging professionals are not properly educated on the procedures and images required in the manufacturer recommended follow-up protocol, my study will better illustrate the need for standardization of imaging procedures.

Hypotheses

1. The average number of images obtained during the three month follow-up HSG will not be significantly different than the number of images that are required in the Essure® protocol.
2. There will be no occurrences of reported technical difficulties or limitations due to the number of images provided for radiologist interpretation.
3. There will be no occurrences of technical errors within the images, including fundal views, blurred images, lack of a marker noting anatomic side, presence of a speculum within the reproductive anatomy, and/or cut off reproductive anatomy.

Methodology

This study was conducted as a mixed-methods, retrospective analysis of hysterosalpingography examinations performed for post-Essure® placement between January 2008 and December 2010. Radiologist records for 130 patients were analyzed to identify the number of images obtained and the reporting of limitations or complications resulting from the number of images captured. A secondary analysis of the images by the author was conducted to report technical issues such as fundal positioning, blurred images, presence of a lead marker within the radiographic field, presence of a speculum within the reproductive anatomy, or cut off of reproductive anatomy. The criteria for an optimal HSG image that was referenced for this secondary analysis was based on information provided in *Hysterosalpingography: a Text and Atlas.*

The sample period from January 2008 to December 2010 was chosen as a convenience sample; beginning in 2008 the prevalence of Essure® follow-up HSGs at this facility has grown, and the idea for this research study was initially proposed in early 2011. No subjects or examinations were excluded.

After IRB approval was obtained, the images and radiologist reports for each patient were initially collected and de-identified. The de-identified records were evaluated by the author, and a spreadsheet was used to record the presence or absence of each image suggested by the Essure® protocol, limitations noted in the radiologists' reports, and any technical errors noticed in the secondary analysis of the images. Key words searched for when noting limitations reported by the radiologists were "limited," "sub-optimal,"

"nondiagnostic," and "un-interpretable." The presence or absence of each variable was independently recorded as (1, present) or (0, absent) in the spreadsheets below.

	A	B	C	D	E	F	G	H
1	Study ID	Image 1 - Prelim	Image 2 - Minimal Fill	Image 3 - Partial Fill	Image 4 - Total Fill	Image 5 - Magnification Right Device	Image 6 - Magnification Left Device	Limitations Indicated on Final Report
2	1							
3	2							
4	3							
5	4							
6	5							

Figure 8 – Data Collection Spreadsheet 1

	A	B	C	D	E	F	G	H
1		Fundal?	Parts of Reproductive system missing?	Obliqued for mags?	Subtraction images?	Grainy/Blurry?	Speculum Present?	Marker?
2	1							
3	2							
4	3							
5	4							
6	5							

Figure 9 – Data Collection Spreadsheet 2

Descriptive statistics were calculated to determine the mean number of images included in all of the studies, the frequency of noted limitations in the radiologists' reports, and the frequency of technical errors in the images.

Chapter Three

Results

Of 428 images obtained in 130 sample exams, 74 exams included a preliminary scout image, 55 exams included a minimal fill image, 88 exams included a partial fill image, 119 exams included a total fill image, 46 exams included a right magnification image, and 46 exams included a left magnification image. Even though the totals for both the left and right magnification views equaled 46, those examinations which included one magnification view did not necessarily include the other (Figure 7).

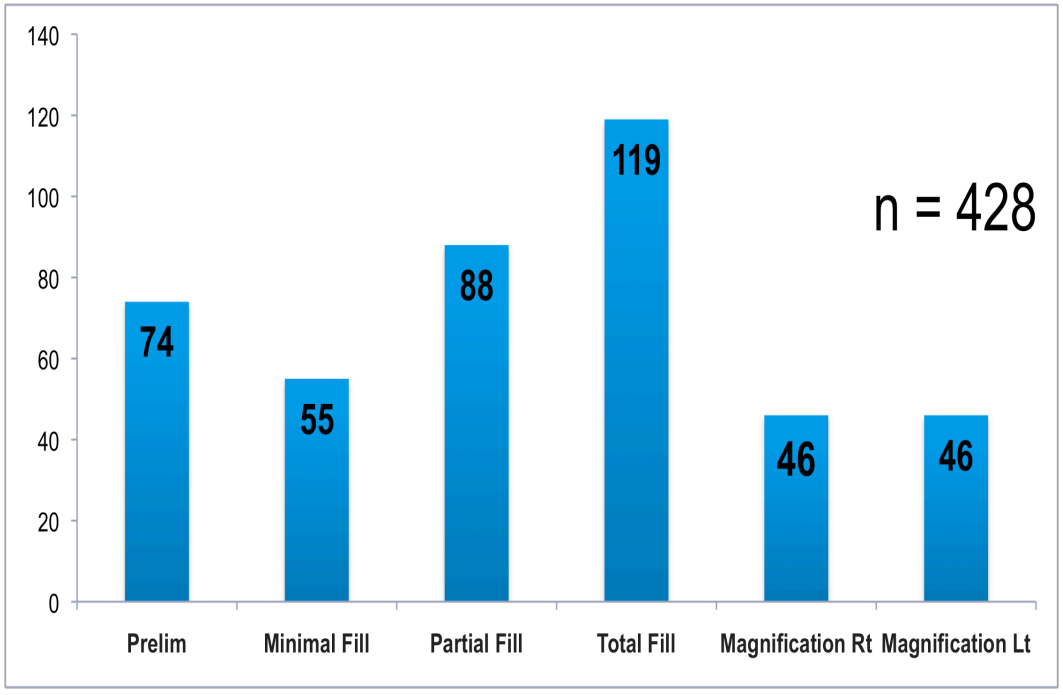

Figure 10 – Image Frequency

Across all examinations, the mean number of images acquired was 3.29. Sixteen cases included only one image, 26 cases included 2 images, 34 cases included 3 images, 27 cases included 4 images, 12 cases included 5 images, and 15 cases included all 6 images. Seventy percent of the cases included 2,3,

or 4 images. However, about 12% of cases only included one image for the radiologist to evaluate (Figures 8 and 9).

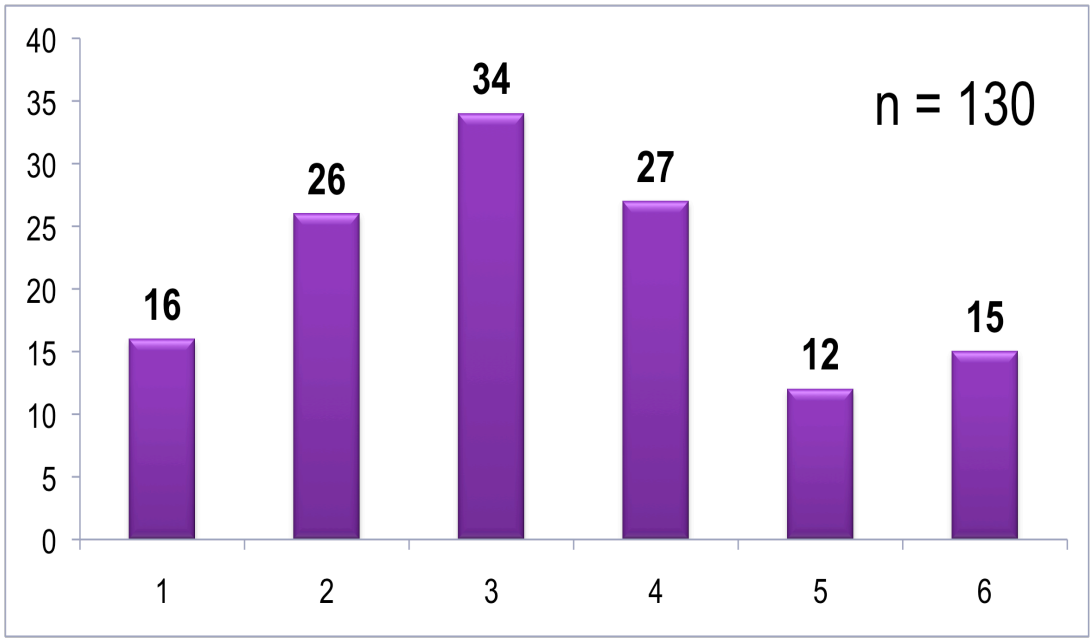

Image 11 – Number of Images Per Examination

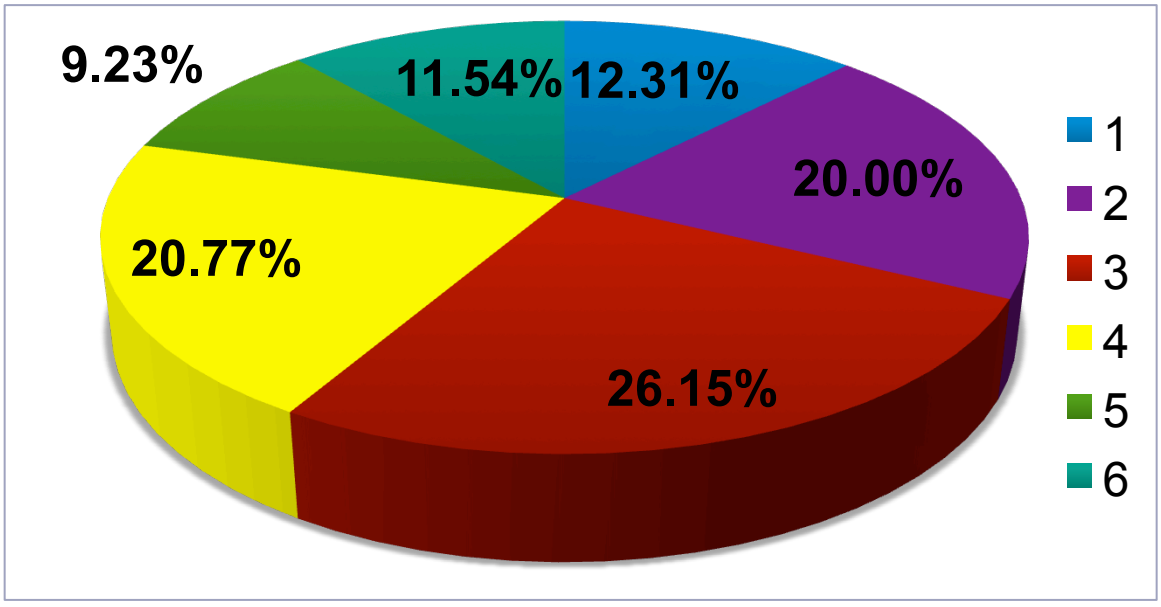

Image 12 – Comparison of the Number of Images Per Examination

Only 9 reports contained mentions of limitations in diagnosis due to the number or quality of the images provided for interpretation. This represents 7% of

the sample population. In four of these reports, the radiologist stated that air-bubbles within the uterine cavity limited the view of the cornua. Three stated sub-optimal visualization of the uterus due to the failure to place the uterus in a true anteroposterior position. One report noted that the evaluation of the devices and potential free spill was limited because only one image was provided for interpretation. Only one report stated that the study was non-diagnostic due to the quality of the images obtained.

Following evaluation of the radiologists' reports, the author conducted a secondary image analysis that was independent of the radiologists' findings. Within this review, it was found that twenty-two percent (29/130) of the cases included fundal images of the uterus. The uterus will naturally lie in a fundal position unless the gynecologist uses a tenaculum to pull down the inferior uterus into a true anteroposterior position. It was also found that parts of the reproductive anatomy including the vagina, uterus, and cervix were clipped off in 28% (36/130) of the cases, and in a further 18% (23/130), the gynecologist failed to remove the speculum prior to exposure, resulting in incomplete visualization of reproductive anatomy. In 9% (12/130) of the exams, one of more of the images was considered blurry during this secondary analysis. The most frequent technical error committed during these exams was failure to use a lead marker to denote anatomic side; 52% (68/130) of cases were not marked with a lead marker.

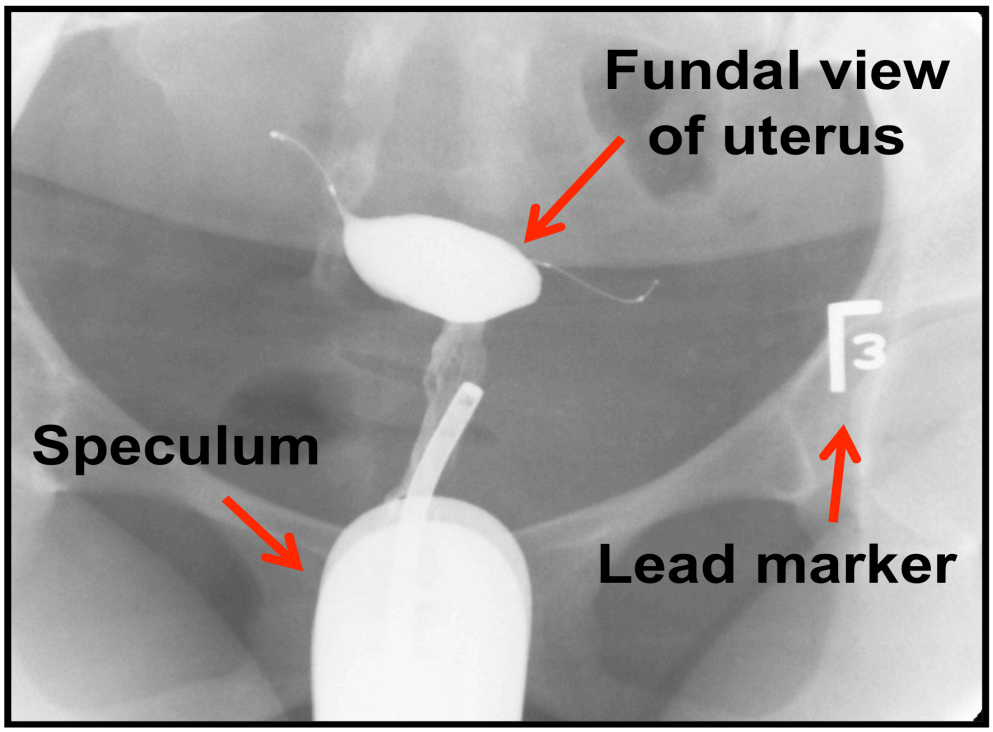

Figure 9 – Technical Considerations

Free spill was diagnosed in five of the 130 patients included in this study. This free spill is characteristic of tubal patency, and these patients were counseled to rely on alternative forms of birth control for another three months until tubal patency is reevaluated at a six month HSG. This rate of tubal patency at the three month period (3.86%) is slightly higher than the national average of 3%. Three of the patients who exhibited free spill from one of their fallopian tubes received three images during their three month follow-up HSG. One patient received two images, and one patient received four images.

Discussion

Research Question 1 – Will the average number of images obtained during the three month follow-up HSG be significantly different than the number of images that are required in the Essure® protocol?

Most studies (12%) provided a total fill image for the radiologist to interpret. This image is the most diagnostic of the images included in the protocol because this volume of contrast provides maximum pressure on the Essure® devices and the fallopian tubes.[2] If any contrast is going to extravasate into the peritoneum, it is usually during this phase of the examination. Patients are advised not to rely on the micro-inserts for contraception if contrast is seen past the distal end of the coils or in the peritoneal cavity, and failure to diagnose this free spill and tubal patency could result in unintended pregnancies.[1]

The right and left magnification views were included the least frequently of all of the protocol images. These images are important because they allow the radiologist to visualize larger and more detailed views of the devices and to determine the relationship of the coil markers to the uterotubal junction. If extravasation is missed on the total fill image, it still may exist and be visible only on these magnification views.

The mean number of images provided for radiologist interpretation per examination was 3.29. This value is clearly much lower than the 6 images suggested by the manufacturer.[1] In only 12% of the examinations were all six images provided for radiologist interpretation, and 12% of examinations contained only one image.

Similar to this study, the research conducted by Wittmer and Famuyide in 2005 showed wide variance in the number of exposures per patient. In that facility, the average number of images acquired was 2.4, compared to 3.29 at the facility in this study. No set protocol was required at the time of the Wittmer study, but those physicians who reviewed the images agreed that additional imaging would have aided in determining device placement and occlusion. Even though this study provided a slightly higher average in the number of images provided for radiologist interpretation when compared to this 2005 study, the average of 3.29 images obtained is still very low when compared to the six images in the protocol.

Research Question 2 – Will be occurrences of reported technical difficulties or limitations due to the number of images provided for radiologist interpretation?

In this study, a very small percentage (7%) of radiologists' reports included mentions of limitations in diagnosis due to the number or quality of images provided. Although many technical errors are being committed, they do not seem to affect the radiologists' ability to interpret the images. There could be some argument that patient dose could be reduced if diagnosis is possible through fewer images, which would be an area for future study.

Among the other research conducted within the United States, in which the FDA requires that the patient undergo a three month follow-up HSG to diagnose tubal occlusion, there is not adequate consistency in the Essure® HSG protocols between facilities. In the 2005 Wittmer and Famuyide study, no specific

protocol was followed for each examination, and an average of only 2.4 images was provided for radiologist interpretation per patient.

In this study, it was shown that these Essure® follow-up HSGs are still fairly infrequent 10 years after this birth control system's FDA approval. With only 130 Essure® HSGs performed within a two year period, they comprise a very small portion of the total workflow for this large mid-west university hospital. Standardization of the images between examinations could assist the radiologists in making a complete and accurate diagnosis of tubal occlusion because they would be evaluating images of consistent appearance and technical quality.

Research Question 3 – Will there be occurrences of technical errors within the images, including fundal views, blurred images, lack of a marker noting anatomic side, presence of a speculum within the reproductive anatomy, and/or cut off reproductive anatomy?

Fundal views of the uterus provide incomplete visualization of the anatomy, which could lead to missed diagnoses of fibroids or polyps. The gynecologist must remove the speculum and employ the use of a tenaculum to pull the uterus down into a true anteroposterior position prior to imaging in order to produce an image of optimal diagnostic quality. During the author's evaluation of the sample images, the position of the uterus was compared to the positioning in examples of optimal HSG images from *Hysterosalpingography: a Text and Atlas*.[7] Those images in which the uterus was considered to be in a fundal rather than a true anteroposterior position were included in the 22% of examinations with fundal images.

Failure to place a lead marker in the radiation field to denote correct anatomic side could lead to incorrect diagnosis of side of free spill. The facility held an educational meeting about the importance of consistency between examinations in 2010; during this meeting, a Conceptus representative educated the imaging staff on the Essure® device and the proper procedures for the company recommended protocol for the follow-up HSG. A policy regarding the mandatory use lead markers has been added since the time of this study to require the use of a lead marker for every examination. Compliance with this policy could be evaluated at a later date.

Most of the literature available on the Essure® system at the time of this study concentrated on the rate of follow-up HSG compliance among Essure® patients. The results of this study cannot be compared to these measures, as only those patients who actually received the follow-up HSG were examined. In addition, there is limited research on these devices within the United States. Although more information and study results are available from foreign sources, other countries allow alternative follow-up imaging techniques and are difficult to compare to the results of this study.

Limitations and Recommendations for Further Research

One possible limitation to this study is the fact that the results can only be applied to a single medical facility because other facilities may employ a different protocol for the three month follow-up HSGs. The follow-up HSG is required by the FDA in order for the patient to rely on the devices for contraception. However, the protocol provided by Conceptus is merely a recommendation. Variations among protocols at different facilities make it hard to apply this study's findings to other facilities that perform Essure® follow-up HSGs. Standardization of the use of the Conceptus recommended protocol across all facilities would be ideal so these examinations can be compared.

In addition, cases were interpreted by a single radiologist, and not all of the cases were read by the same radiologist. Therefore, there was no way to compare the radiologists' evaluations. This study relies on the reporting of limitations by only one radiologist per case, and because this radiologist was not the same for all cases, variations among reporting thoroughness and style could affect the frequency of stated limitations. Many cases provided images in which the author found technical issues, but the radiologist provided a reading and diagnosis.

A single senior radiography student completed the secondary evaluations of the images for technical limitations, which could be considered an additional limitation to this study. If a secondary evaluator had reviewed the images, the results of the two evaluations could have been compared to increase the validity of the results for this set of variables.

The software associated with the fluoroscopic equipment used in this study allows images to be deleted before they are sent to the picture archival and communications system (PACS). Although imaging personnel have been instructed to save all images and send them to PACS for radiologist interpretation, the possibility that some images not deemed diagnostic could be deleted must be considered.

The limitations of the study's IRB approval do not allow for a longitudinal evaluation of patients, and there is no way to track complications missed during the follow-up HSGs. This factor would increase the importance of my findings that an average of 3.29 images were provided for interpretation. This would be an area that could lead to further research with these procedures.

Conclusions

Many technical errors are being committed during the follow-up HSG examinations for Essure® placement. The number and quality of images provided for radiologist interpretation varied widely from examination to examination. At this major mid-west university hospital, radiologic technologists are responsible for fluoroscopy image acquisition during HSG examinations. However, there does not seem to be proper consistency between the images captured from examination to examination.

In 2010, a Conceptus representative held a meeting at this facility about the appearance and function of the Essure® devices as well as the importance of adherence to the manufacturer suggested protocol. However, more education about the importance of consistency is necessary to ensure optimal quality images for diagnosis. Each follow-up HSG for Essure® placement and occlusion should include the same six images from the manufacturer suggested protocol, with limited artifacts or technical compromises.

Regardless of the number of images acquired, diagnosis was possible in all of the sample cases. This could warrant further research to determine if patient dose can be lowered through the reduction of images required in the protocol.

Further research could also be conducted on improvements in HSG examinations done for Essure® placement since the 2010 interventional meeting. In addition, other variables, such as the gynecologist and imaging personnel

conducting the examination or patient demographics, could be included to further understand the causes of variation between examinations.

Glossary

hysterosalpingogram (HSG) – a nonsurgical method for evaluating uterotubal pathology, in which radiographic contrast is instilled transcervically in the uterine cavity and fallopian tubes followed by fluoroscopic examination as a means of defining shape and size of the uterine cavity and tubal patency

anteroposterior – from front to back of the anatomy of interest, for example, during a chest x-ray the back is placed against the receptor and the x-ray tube is in front of the patient

intramural tubal lumen – within the walls of the fallopian tube lining

uterine cornua - the portion of the uterus to which the intramural section of the fallopian tube connects, forms a horn shape

utero-tubal junction – the connection of the fallopian tube and uterus, occurs at the uterine cornua

nitinol – alloy of nickel and titanium

polyethylene terephthalate - synthetic resin made by copolymerizing ethylene glycol and terephthalic acid, widely used to make polyester fibers, causes a benign inflammatory response in the fallopian tubes

vasovagal - temporary fall in blood pressure, with pallor, fainting, sweating, and nausea, as a result of stress

salpingitis – inflammation of a fallopian tube, can be related to pelvic inflammatory disease

dysmennorhea – menstrual pain, painful periods, dysfunctional uterine bleeding

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